National Confectioners Association
ALWAYS A TREAT

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Via Email to P65Public.Comments@oehha.ca.gov and monet.vela@oehha.ca.gov (Subject: "Calculating Exposure")

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Re: **Response to Request for Public Comments on OEHHA's Proposals to Amend Proposition 65 Calculating Level of Exposure Regulations for Reproductive Toxicants (Section 25821(a) and (c))**

To Whom It May Concern:

This is submitted on behalf of the National Confectioners Association (NCA) and its members with respect to the California Office of Environmental Health Hazard Assessment's (OEHHA's) pending proposal to amend both Sections 25821(a) and 25821(c) of Title 27 of the California Code of Regulations. NCA also endorses and incorporates by reference the comments being submitted on this proposal by the California Chamber of Commerce Coalition which urge OEHHA not to proceed with its proposals.

Background. The NCA is the not-for-profit trade association of the confectionery industry. NCA represents more than 250 companies that manufacture chocolate, confectionery, gum and mints in the United States and another 250 companies that supply those manufacturers. The majority of our members are small and medium-sized companies. The confectionery industry includes hundreds of small, family-owned businesses that pass on candy-making expertise from generation to generation. Nearly 200 confectionery manufacturers are based in and/or have facilities and operations in California. Notable California confectionery companies include Jelly Belly, Gimbals, Guittard, Ghirardelli, See's, American Licorice and many more. For every job that is created in confectionary, another seven are supported in related industries. Confectionery companies employ approximately 7,000 people in the State California (per census data) with annual shipments valued more than $1.7 billion.

In both the past and the present, NCA members and their customers have been subjected to bounty hunter claims initiated by a variety of Proposition 65 plaintiffs. These claims have often included allegations that the confectionary in question requires reproductive harm warnings under Proposition 65 due to trace levels of lead, cadmium, and/or other listed chemicals. Some of these actions have been accompanied with public relations campaigns that are designed to provoke media attention and scare consumers, including with suggestions that the ordinary consumption of safe and enjoyable confectionary may result in birth defects and other reproductive harm. To the contrary, as data NCA has previously shared with OEHHA establishes, typical consumers partake of confections periodically and in moderation and not in the amount or frequency that would result in any such effects.

NCA members often cannot afford to litigate Proposition 65 claims based on establishing an affirmative defense in contested litigation because of the time and costs involved. Nor do many of them have the resources necessary to counteract public relations and other scare tactics even where the allegations about reproductive harm effects arising from the consumption of their products are not supported by historical experience, epidemiology, or sound science. Even potential regulatory processes, such as safe use determinations, are not a viable option for those concerned – nor should such be necessary where there is no evidence of reproductive harm from the consumption of the products in question and where they have more generally been recognized as safe by food regulators here in the United States and abroad.

General Comment. OEHHA has not responded to NCA's comments on its 2015 pre-regulatory proposals for modifying Section 25821, either directly or in its current Initial Statement of Reasons (ISOR). Its newly formally proposed modifications to Sections 25821(a) and 25821(c) still are not based on sound science or supported by an adequate analysis or record, and will have the effect of imposing costs on NCA members while substantially undercutting, if not completely voiding, the Section 25249.10(c) statutory defense to which NCA members are entitled. As a result, such modifications would exceed OEHHA's authority and will not further the purposes of the Initiative. The newly proposed rules should therefore not be adopted in the first instance and should instead be promptly withdrawn.

Specific Comments.

Proposal on Section 25821(a). NCA urges OEHHA to drop or at least substantially modify its proposal for amending Section 25821(a) of the Proposition 65 regulations regarding the averaging of test results on a food product to determine the "level in question."

Specifically, OEHHA's premise that a warning should be based on a single exposure that "a consumer might reasonably receive from a product purchased at a specific time and place" is inconsistent with the Initiative and the voter's intent in adopting it. Proposition 65 was not enacted to assure *each* Californian that a reproductive harm warning would be given to them

based on the level of a listed chemical *they* might happen to encounter in a *particular* package or container of a food item purchased on a *particular* day. Instead it was adopted to assure *all* Californians that they would receive such a warning if the *typical* consumer among them was exposed to a sufficiently high level of the listed chemical from the food product, as it is *typically* presented in the California marketplace.

For chemicals in food products that do not present acute reproductive effects from a single isolated exposure, averaging results across a reasonable period of time (such as its typical shelf life) *and* based on the variety of facilities that may have produced or manufactured the product or its constituent ingredients better reflects the level of the chemical that a consumer may *typically* be exposed to from the food product as purchased from the marketplace. Confections which meet FDA's requirements simply do not present acute or reproductive effects due to single isolated exposures. Therefore, changing the Proposition 65 regulations for calculating levels in question for determining the need for reproductive warnings based on such highly isolated, rather than marketplace typifying, data as OEHHA proposes does not facilitate the implementation of the statute in the manner the voters intended.

Indeed, because the one-thousand-fold safety factor is already incorporated into the MADL as an extreme measure of conservatism relative to the potential reproductive risk, adding further conservatism to the level in question calculation based on isolated circumstances rather than what is typically presented in the marketplace over an appropriate period of time goes too far and is just a recipe for even more meaningless warnings.

In addition, OEHHA is wrong to assume that different facilities and sources add chemicals to foods, especially confections, in amounts which may be materially different due to contaminants coming from their equipment or physical environments. While the facilities or ingredient sources utilized by one producer may vary from that utilized by others, to the extent they are producing foods to be legally sold in the United States, they all must employ good manufacturing practices and preventive controls as prescribed in FDA's regulations. Those regulations thereby prevent the addition of deleterious chemicals being added to the food so there is no reason why test results should not be averaged to reflect the level of a chemical that a consumer randomly selecting the food product from the marketplace may face during a reasonable time period relative to their consumption.

Indeed, OEHHA's ISOR even acknowledges that there is bound to be natural inherent variation in the level of chemicals listed for reproductive harm in the food. But it assumes without basis that food is contaminated with reproductive toxicants due to the nature of the facilities in which it or its ingredients are manufactured. In fact, the ISOR presents no evidence that the extent of natural variation of the chemical in food does not overwhelm differences, if any, in the level of the chemical resulting from variation in the producer's or ingredient supplier's manufacturing facilities or sourcing practices.

The legal implications of OEHHA's proposed Section 25281(a) are also vast – food producers will not be able to establish the "level in question" based on the inherent variability that may be presented by their relevant product in the marketplace but instead would only be able to do so if they establish separate and sufficiently representative testing programs in *each* one of their facilities and in each ingredient supplier's facilities. Such an approach is both pragmatically and economically prohibitive. The proposed regulation therefore is divorced from the reality of its implications, and the ISOR wrongly concludes that the proposed regulation will not have a significant statewide adverse economic impact directly affecting businesses – the proposed rule therefore necessitates a full economic impact analysis.

The practical effect of the testing and data collection implications of this proposed change in the regulations, and one that contradicts the statute and the voter's intent, is to effectively eliminate the Section 25249.10(c) defense for confectionary manufacturers and most other food businesses. As is clear from the ballot arguments, this "defense" is what makes sense of the statute – if it is, as a practical matter, unavailable because it is unprovable, exposure to even a detectable particle of a reproductively-listed chemical in a food will require a Proposition 65 warning and that is *not* what the voter's adopted.

Proposal on Section 25821(c). NCA also urges OEHHA to abandon its proposal to require that the rate of intake or exposure for average users of a product be calculated only as an arithmetic mean, regardless of the underlying distribution of the data in question. This conflicts with the prevailing best practices of statisticians and academics notwithstanding OEHHA's pointing in the ISOR to select uses of arithmetic means by others on occasion.

OEHHA's rational for this proposal – that the arithmetic mean is more familiar – is also completely non-scientific and, hence, flawed. Rather than providing equal weight towards a measure of central tendency as geometric means do, arithmetic means overvalue the high end of a statistical distribution and undervalue their low ends absent the distribution being a perfect bell curve, which, as the ISOR recognizes, food consumption distributions almost never do. OEHHA's Section 25821(c)(2) proposal would therefore disproportionately impact confectionary producers because confections are a product as to which consumption patterns may be particularly skewed, or in other words, significantly distorted from a normal bell curve that is necessary to scientifically justify use of an arithmetic mean.

Indeed, as the data NCA submitted with its 2015 comments demonstrated, a very small percentage of the population of confectionary consumers may consume significantly more than the mode, vast bulk of the population, or the typical eater of the product in question. While the majority of confectionery consumers incorporate candy in moderation, a small percentage consumes a substantially higher amount. It is well-recognized science that if the outlier is allowed to skew the average, then the information going to consumers will misinform most of them. That does not reflect the voter's intent in enacting Proposition 65 and is bad public policy.

Finally, as to this proposed change in the regulations also, the record is devoid of any economic impact analysis. If the result of it is to command warnings in more circumstances, those warnings have real costs that require analysis, both in terms of implementation as well as in terms of the confusion caused to the public.

We appreciate the opportunity to offer our views and comments on these issues and again strongly urge to OEHHA withdraw these two counter-productive proposals in their entirety.

Sincerely yours,

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